K090493

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AUG 07 2009

Section 5

510(k) Summary of Safety and Effectiveness

Signal™

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Zargis Medical Corporation is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Zargis Medical chooses to submit a summary of information respecting safety and effectiveness.

Trade Name:	Signal™
Common Name:	Electronic Stethoscope and Phonocardiograph
Regulation Number:	21 CFR 870.1875, 870.2390
Classification Name:	Stethoscope, Electronic; Phonocardiograph
Product Code:	DQD, DQC
Regulatory Class:	Class II
Submitter Information:	Zargis Medical Corporation 2 Research Way, 1st Floor Princeton, NJ 08540 Tel: 609.734.4747 Fax: 203.547.6103
Summary Prepared By:	John Kallassy President/CEO
Date Prepared:	February 20, 2009
Predicate Devices:	1) CADIscope Electronic Stethoscope and Integrated ECG, K990809 2) eStation Model DR200 Electronic Stethoscope, K001788 3) Meditron II, thestethoscope system, K013725

Device Description: Signal™ is an electronic auscultation device intended to acquire, record, and display heart sounds and other body sounds. Signal includes a single-lead electrocardiograph to produce an ECG on the laptop monitor to enable the health care

professional to synchronize the phonocardiogram with the beginning of the heart cycle.

The device also allows the sharing of data through the Internet and provides a means to attach patient information to the stored sound files.

Intended Use: Signal is a noninvasive, non-interpretive, device indicated for the following:

Signal is an electronic device intended to support the physician in the evaluation of heart sounds, lung sounds, bowel sounds and other acoustic signals in patients. The device allows for the recording of multiple, simultaneous acoustic signals and includes a single-lead electrocardiograph that produces a visual display of the electrocardiogram (ECG) on the PC monitor to enable the healthcare practitioner to synchronize the phonocardiogram with the beginning of the heart cycle. The ECG is not intended for diagnostic use. The device also allows the sharing of data through the Internet and provides a means to attach patient information to the stored sound files. Signal is intended for use by healthcare professionals only.

Substantial Equivalence: The Signal device is similar in design/technological characteristics, indications for use, and performance characteristics to the currently cleared electronic stethoscopes cited above.

Safety and Performance: A comprehensive list of verification and validation testing was performed in accordance with Zargis' Design Control procedures.

Non-clinical performance testing has been conducted to demonstrate the performance of the Signal device and that it meets its intended use. Specifically, the Signal has been assessed for applicable biocompatibility testing, electrical safety and EMC testing, and software verification and validation testing. All product specifications were met.

Conclusion: Based upon the indications for use, technological characteristics and safety and performance testing, the Zargis Signal device has been shown to be substantially equivalent to the currently cleared predicate devices under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

AUG 07 2009

Zargis Medical Corp.
c/o Mr. John Kallassy
CEO
2 Research Way, 1st Floor
Princeton, NJ 08540

Re: K090493
Trade/Device Name: Signal™
Regulatory Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II (Two)
Product Code: DQD
Dated: July 31, 2009
Received: August 4, 2009

Dear Mr. Kallassy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090493

Section 4

INDICATION FOR USE

510(k) Number (if known): ~~Not Assigned~~ K090493

Device Name: Signal™

Indications for Use:

Signal is an electronic device intended to support the physician in the evaluation of heart sounds, lung sounds, bowel sounds and other acoustic signals in patients. The device allows for the recording of multiple, simultaneous acoustic signals and includes a single-lead electrocardiograph that produces a visual display of the electrocardiogram (ECG) on the PC monitor to enable the healthcare practitioner to synchronize the phonocardiogram with the beginning of the heart cycle. The ECG is not intended for diagnostic use. The device also allows the sharing of data through the Internet and provides a means to attach patient information to the stored sound files. Signal is intended for use by healthcare professionals only.

Prescription Use: X AND/OR Over-The Counter Use:

(Per 21 CFR 801 Subpart D) ..... (Per 21 CFR 801 SubpartC)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090493